Treatment of Complex Regional Pain Syndrome type I; A randomised, single-blind, placebo-controlled study with multiple rounds of S(+)-ketamine infusions.

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Multiple rounds of S(+)-ketamine infusions will give more profound and prolonged pain relief compared to a single infusion of S(+)-ketamine.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21045

Bron
Nationaal Trial Register

Verkorte titel
The KetKet study, pilot

Aandoening

Complex Regional Pain Syndrome type I (CRPS type I)
Complex Regionaal Pijn Syndroom type I (CRPS type I)

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Department of Anesthesiology
Overige ondersteuning: TREND, Delft

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Pain scores (NRS)
- Allocation scores patients, whether they received S(+)-ketamine or placebo.

Toelichting onderzoek

Achtergrond van het onderzoek

The treatment of Complex Regional Pain Syndrome type I (CRPS) with S(+)-ketamine showed good pain relief for weeks. However, in most patients, the pain returns to baseline levels. Open label studies suggest a longer duration of pain relief when ketamine is administered more than once. In this randomised, single-blind, placebo-controlled pilot study, we adminster S(+)-ketamine once or twice to test whether pain relief is prolonged with multiple infusions of S(+)-ketamine.

Doel van het onderzoek

Multiple rounds of S(+)-ketamine infusions will give more profound and prolonged pain relief compared to a single infusion of S(+)-ketamine.

Onderzoeksopzet

- Baseline measurements before first admission.

- Measurements, on average 3 times a day, during admissions.

- Weekly measurements between and after admissions, until baseline is reached, afterwards on average monthly measurements.

- Follow-up up to 52 weeks from first admission.

Onderzoeksproduct en/of interventie

Patients are randomised into 3 groups.
Admissions will take place in week 1 and 4 or week 1 and 13 of the study. All patients are admitted twice for 5 days, during which they will receive intravenous S(+)-ketamine or active placebo midazolam, both in an increasing subanesthetic dose based on weight.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. CRPS type I diagnosis according to the IASP-criteria;

2. NRS spontaneous pain score of 5 or higher;

3. Age is between 18 and 70 years;

4. Patients must give a written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients who are not able to give informed consent;

2. Patients suffering from other syndromes/diseases interfering with pain ratings;

3. Patients who previous have had ketamine continuous infusion;

4. Patients with co-morbidity such as:
kidney disease, severe liver disease, nerve damage in the affected area, increased intracranial pressure, infectious disease, epilepsy, a psychiatric illness, thyroid disease, cancer, cardiac disease, pulmonary disease, severe or uncontrolled hypertension, aneurysm, glaucoma, history of cerebral vascular accident (CVA) < 1 year;

5. Patients who are pregnant.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-11-2008
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-11-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1479
NTR-old	NTR1550
Ander register	TREND, Delft (NL); BSIK03016 : P08.106
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A